Quality Assurance Program
For Hospital Based Point of Care Testing

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Pathology Manager, QA Specialist
Disclosures

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• Financial – Honorarium – Speaker for COLA Laboratory Director’s Symposium; Speaker for AACC webinar
Objectives

At the end of the session, participants will be able to:

• Develop a QA program for the testing performed
• Monitor the performance of point of care tests
• Assure appropriate training of clinical staff
• Utilize various tools to monitor and assess quality
List of Current POCT

- ACT-LR, ACT Plus
- Specific Gravity
- Creatinine
- INR
- Hgb
- Urine HCG
- Urinalysis
- HBA1c
- Glucose, whole blood
- O2 Saturation
- pH
- Strep A
- Rapid HIV 1/2 Antibody
- Rapid HCV
- Urine Drug Screen
- PPM (Fern, KOH, Sperm-Qual, Postcoital mucus, Urine Sediment)
- Tear Osmolality
- Fecal Occult Blood
Importance of POCT

- Impact on Patient Centered Care
- Potential for faster patient treatment
- Inpatient and Outpatient Testing
- Enhance achievement of national quality benchmarks
- Connectivity – data analysis, quality oversight, standardization/harmonization
Ongoing Monitoring

• Mock inspections and intracycle monitors
  – Follow regulatory body checklist
• Enroll in a CLIA approved Proficiency Testing Program
• Perform semi-annual patient correlations
• Hopkins Event Reporting Online (HERO) - submit lab issues and other patient safety concerns
• Safety Officers program/CUSP
  – Safety officers are engaged in the unit practices. Safety Officers include nurses, medical assistants, unit managers, providers
Ongoing Monitoring

- Schedule internal audits or inspections to each unit
  - Inspect all storage areas where POC supplies are kept
  - Look for open and expiration dates on all POC containers and/or test kit/devices
- Observe testing and sample collection techniques
- Review all quality control and patient documents
- Inspect devices/instruments
- Interact with testing personnel on a regular basis
Ongoing Monitoring

- Host a monthly meeting with the major lab vendors such as Quest, Lab Corp and Johns Hopkins Medical Lab
  - Review cancellation reports
    - Trends in cancel reasons
    - Education
    - Supplies
    - Courier schedules
    - New Test Codes
    - New Specimen Collection Devices
Developing a QA Program

- Waived
- Moderate Complexity
- Provider Performed Microscopy
- High Complexity
CLIA Expectations - Waived

- Enroll in the CLIA program;
- Pay applicable certificate fees biennially
- Follow manufacturers' test instructions
- Allow CLIA inspections
  - Collect information on waived tests;
  - Determine if a laboratory is testing outside their certificate
  - Investigate an alleged complaint
  - Determine if the performance of such tests poses a situation of immediate jeopardy

READY?
SET?
TEST!

PATIENT TESTING IS IMPORTANT.
Get the right results.

http://wwwn.cdc.gov/clia/Resources/WaivedTests/
CLIA Expectations – PPM & Moderate Complex

• Moderate
  – Same as waived criteria
  – Documented competency and training
  – Documented highest level of education

• PPM – only providers can perform
  – CAP, TJC and COLA – specific standards to follow
  – PT not required, alternative assessment allowed, at least twice per year

PROVIDER-PERFORMED MICROSCOPY PROCEDURES
A Focus on Quality Practices

http://www.cdc.gov/clia/Resources/PPMP
Ambulatory QA Plan

Details from an Ambulatory Laboratory QA Plan
Staff Training and Competency Ambulatory

- New Hire training during orientation
- Annual competency checklists and/or computer based training (CBT)
- Quiz
- QC performance at least once a year
- 2 of the 6 key CLIA elements – Waived
- 6 key CLIA elements – Moderate
- Technical, supervisory and testing personnel requirements

*Key is engaging testing personnel
Vendor support/ training
Ambulatory

• Utilizing Vendor Reps for support in training
• Vendor reps are brought into sites to perform on site training with our competency checklist
• Vendor reps have a great report with sites and reach out several times a year for support
Proficiency Testing
Ambulatory

• Example of failed proficiency leading to investigation of POC device
  – Corrective action plan – repeat sample, vendor representative training with competency checklist, correlation samples, Technical service rep download data and evaluate
  – As a result of failed QA specimens, we isolated one Afinion, the device that we use to measure HBA1c, needed to be replaced

• HBA1c, Hgb, Strep A, pH, fecal occult blood, glucose
Quality Control Testing
Ambulatory

- Documenting internal and external controls
- Follow manufacturers instructions in package inserts
- State and Federal guidelines
- External QC materials often made by company that does not make test kits
- IQCP and risk assessment
Example of EMR documentation

POCT hCG, Urine, Qualitative

<table>
<thead>
<tr>
<th></th>
<th>Range</th>
<th>3wk ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>POC HCG, Urine</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>POC QC Performed?</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

- Internal QC documented with each POC test entered into patient chart
- Example is from manual test entry where interface is not in place
Example of Paper Logs

Johns Hopkins Community Physicians

QuickVue One Step hCG Urine Pregnancy Test Control Log
External Controls are done with each new Lot # and each new shipment

| Date | Kit Lot Number | Kit Expiration Date | POSITIVE CONTROL: (POS) | NEGATIVE CONTROL: (NEG) | SIGNATURE | Problems? (Y/N)
If Yes document below |
<table>
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<tr>
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<tbody>
<tr>
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<td>Lot #: __________________</td>
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<td>Exp Date: ______________</td>
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DATE | PROBLEM | ACTIONS
-----|---------|----------
      |         |          

Actions include but are not limited to: re-testing the specimen with a new kit, using a kit from a new box, using a new lot number, informing manager.
# Example of Paper Logs

**QuickVue One Step hCG Urine Pregnancy Test Control Log**

External Controls are done with Each New Lot # and Each New Shipment

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Semiannual Lab Inspections
Ambulatory

Checklist based on CAP, TJC and COLA guidelines to include:
- Point of care areas
- Phlebotomy areas
- Specimen collection containers
- Centrifuges and microscopes
- QC logs for every POCT
- Tracking logs
- Refrigerator logs

- Eyewash logs
- Testing supplies in date and marked opened
- Availability of procedures (printed or intranet)
- Competency Checklists/Computer Based Training Modules
- Lab environment
- Record retention
Correlations

Ambulatory

- INR
- HBA1c
- Hgb
- Chol
- AST/ALT
- Chem 8
Hospital QA Plan

Details from a Hospital POC QA Plan
Moderate Complex
Provider Performed Microscopy
Site Visits
Hospital

• Some units are visited twice per week
• Waived testing once per month
• Opportunities for improvement easily identified and addressed with frequent site/unit visits
• Establish relationship with testing personnel
Patient Correlations
Hospital

- Same analyte with different methodologies
- Same analyte at different sites
- Same analyte with different instruments
- At least once every six months
- Opportunities to identify meters that don’t correlate
Patient Tracer Hospital

- Periodic
- Randomly selected patient care areas
- Trace from test result on the POC meter to the patient record (EMR)
- Opportunity to identify clerical or systematic errors
Environmental Rounds Hospital

- Conducted by Health, Safety and Environment Department
- Twice a year
- Unannounced
- Opportunity to identify compliance issues for Institution, local, state or federal regulations
- Corrective action plans are submitted to DHMH
Mock CAP Surveys
Hospital

- College of American Pathologists, CAP Standards
- Continuous Quality Improvement (CQI) Office recruits system wide staff volunteers to conduct Mock Surveys
- Corrective Action Plans are submitted to CQI for documentation purposes
- Opportunity to identify and correct issues before CAP inspection
Quality Control Review
Hospital

• Monthly review
• Some manual via paper logs
• Some electronic via interface
• Opportunity to identify system trends
• Future: looking at middleware solution for electronic entry and monitoring of all manual POCT
PPM – Provider Performed Microscopy

CLIA Sec. 493.1365 Standard; PPM testing personnel responsibilities.


- Utilized by providers who bill for PPM tests complete these modules
PPM – Provider Performed Microscopy

• Providers, including mid-level providers complete modules
• Initial training
• Annual training once every 6 months
• MTS – reports for completion
• Ability to assign modules for only those tests performed
Identifying QA Opportunities
Ambulatory Sites

• Quality assurance opportunities can be identified by monitoring reports or through other tracked and trended issues
• Develop a corrective action plan for deficits identified
• Monitor the process post-corrective action implementation
Future Growth Hospital Program

- Standardized interface platform for Point of Care tests across 5 Hospitals and Ambulatory sites
  - Will allow for quality indicators across the enterprise
- Standardized electronic medical record
  - Primary care and specialty care access
- Standardized laboratory information system
  - Harmonized test panels
- Standardized testing platforms
  - Chemistry and Hematology lines
Summary

A comprehensive Quality Assurance Program includes:

– Continuous Quality Improvement
– Staff training and ongoing competency assessment
– Monitoring program specific to the test(s) performed
– Ongoing quality assurance assessments with appropriate corrective plans and interventions
Questions

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